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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,878	06/17/2005	Feng Ni	11342-1	8274
25277 7590 07/06/2007 NATIONAL RESEARCH COUNCIL OF CANADA 1200 MONTREAL ROAD BLDG M-58, ROOM EG12 OTTAWA, ONTARIO, K1A 0R6 CANADA			EXAMINER BORIN, MICHAEL L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 07/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/500,878	Applicant(s) NI ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-14, 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9, 15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/11/2005</u> . | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### **Status of Claims**

Claims 1-19 are pending. Claims 17-19 are added.

Response to restriction requirement filed 05/14/2007 is acknowledged. Applicant elected, without traverse, Group II, claims 5-9,15. In addition, claims 17-19 are added as claims dependent on claim 5.

Claims 1-4, 10-14, 16 are withdrawn from consideration as being directed to non-elected Groups. Cancellation of claims directed to non-elected invention(s) is requested.

### ***Information Disclosure Statement***

Applicants' Information Disclosure Statement filed 08/11/2005 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9,15, 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

- A. The phrase "ligand ...with a nucleus" is not clear. The terms "nucleus" or "nuclei" are not defined in the specification and the meaning of "nucleus" as related to a ligand is not clear. Does the meaning of the "nucleus" encompasses "nucleus" as in "cell nucleus"?
- B. Claim 5, step (b): The phrase "said off values " is not clear. Is  $k_{off}$  values are meant instead? Please clarify.
- C. Claim 8: The claim is a dependent claim of claim 5, the latter being drawn to a (i.e., single) ligand and determining dissociation rate constant for said ligand. Claim 8, however, encompasses embodiments wherein the ligand is not a single molecule, but rather is a "mixture of polypeptides". Then, it is not clear dissociation rate constant for transient complex of which polypeptide is being determined.
- D. Claim 15: The abbreviation CPMG is not clear and not defined in the specification.
- E. Claim 19: The claims addresses concentrationsg of target moleculesg. Is the same (e.g.,as in claim 18) or different target molecules are being addressed?

***Claim Rejections - 35 U.S.C. § 101***

The following is a quotation of the 35 U.S.C. § 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

4. Claims 5-9,15,17-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a computational process for determining a dissociation rate constant for a transient complex of a ligand with target molecule.

To be statutory, an invention must be directed to one of statutory categories enumerated in 35 USC § 101, or must produce a result which is useful, and tangible, and concrete. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself.

The instant claims do not include any tangible result. The instant claims are drawn to a method wherein the last step is extracting a  $k_{off}$  values - the claims do not include any indication that the final result has been communicated to the outside world or made otherwise readily accessible. Since the instant claims do not necessarily arrive at a result or communicate a result, the instant claims do not include a tangible result. Amending the claims to recite the output of the result of the method is suggested.

***Conclusion.***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.



Primary Examiner

Art Unit 1631

mlb